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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,501	08/09/2000	Susan Acton	MNI-132CP3	5106

959 7590 07/25/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
CHISM, BILLY D

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,501	ACTON ET AL.	
	Examiner	Art Unit	
	Billy D Chism	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to nucleic acid, classified in class 536, subclass 23.1.

II. Claims 2-7 and 17, drawn to polypeptide, classified in class 530, subclass 350+.

III. Claims 8-16, drawn to a fusion polypeptide, classified in class 530, subclass 300+.

IV. Claims 18-19, drawn to method of making polypeptide of Group II, classified in class 435, subclass 70.1+.

V. Claim 20, drawn to method of making protein of Group III, classified in class 435, subclass 70.1.

VI. Claims 21-37, drawn to methods of identifying an ACE-2 therapeutic, classified in class 435, subclass 7.4.

VII. Claim 38, drawn to method of modulating ACE-2 activity, classified in class 435, subclass 7.4.

VIII. Claims 39-41, drawn to methods of treating and preventing blood pressure or disease or disorder, classified in class 514, subclass 1+.

IX. Claim 42, drawn to method of determining risk of developing a disease or condition caused by aberrant ACE-2 activity, classified in class 435, subclass 7.4.

X. Claim 43, drawn to method of identifying ACE-2 polypeptide substrate, classified in class 435, subclass 7.4.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I is related to the invention of Group II in that the nucleic acid of Group I encodes for the protein of Group II. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The inventions of Group I and III are independent and distinct, wherein the products of the two groups are physically and functionally distinct chemical entities.

The product of Group I is related to the method of Group IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid may be used in hybridization assays, PCR or sequence reaction.

The product of Group I is independent and distinct from the methods of Group V, wherein the nucleic acid of Group I can be used neither in the method of Group V nor can it be made by the method of Group V.

The product of Group I is independent and distinct from the methods of Group VI, wherein the nucleic acid of Group I is neither used by nor made by the methods of Group VI.

The product of Group I is independent and distinct from the methods of Groups VII-X, wherein the nucleic acid of Group I is neither used nor made by the methods of Groups VII-X, and therefore, the Groups are patentably distinct.

The products of Groups II-III are distinct wherein they are different in structure and function, and therefore are patentably distinct.

The product of Group II is related to the methods of Group IV as a product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed may be isolated from its natural source or made by chemical peptide synthesis.

The product of Group II can be neither made nor used in the methods of Group V, and therefore, the two Groups are patentably distinct.

The product of Group II and the methods of Groups VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Group II can be used for immunoassays, antibody production, molecular weight markers or as a class of controls.

The product of Group III is neither made nor used by the methods of Group IV, therefore the two groups are patentably distinct.

The product of Group III is related to the methods of Group V as a product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed may be isolated from its natural source or made by chemical peptide synthesis.

The product of Group III and the methods of Groups VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Group II can be used for immunoassays, antibody production, molecular weight markers or as a class of controls.

The methods of Groups IV-X are independent and distinct, wherein the methods of the groups have different endpoints. Therefore, the groups are patentably distinct.

Group I contains sequences to different nucleic acids. Applicants are required under 35 U.S.C. 121 to elect a single disclosed nucleic acid sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

B. Dell Chism

18 July 2002